510(k) SUMMARY
(as required by 807.92(c))

MAY 17 2012

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Submitter of 510(k):
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Date of Summary: March 26, 2012

Trade/Proprietary Name: HeartCheck ECG Pen with GEMS Home

Classification Name: Class II

Product Code: DPS

Regulation: 870.2340

Intended Use:

The HeartCheck ECG Pen with GEMS Home is a telemedicine based solution that is intended to enable adult patients to record, store, transfer and display single channel ECG waveforms while involved in everyday activities anywhere. The HeartCheck ECG Pen combined with GEMS Home enables the person to send their ECG recordings to a medical service for review and interpretation by a qualified health service professional such as a physician. GEMS Home use is not intended to substitute for a hospital diagnostic ECG test. The software and hardware are not intended for recording and transmission of user's ECG signal simultaneously. Patients with implanted pacemaker or defibrillator are not recommended to use this device. GEMS Home is a simple software user interface with ECG trace viewing function.

Device Description:

The applicant device HeartCheck ECG Pen is a handheld device, which can record cardiac event data and display the data in a clear and precise waveform.

The ECG Monitor is made up of signal input unit, signal amplify unit, CPU, Display unit, power unit and storage chip. They are all in one PCB that is designed and made by our manufacturing partner Beijing Choice Electronic Technologies.

The HeartCheck ECG Pen is activated by the user whenever symptoms are experienced. The recorded data serves as reliable evidence and are later shown to physicians or other health care professionals for confirmation of these symptoms. When a user feels that a cardiac event is occurring, the utilization of HeartCheck ECG Pen has the feature of recording this real time data that is normally difficult to capture.

The applicant device has a "data upload" function which is controlled by hardware; it can transmit the data measured by the device to a computer via the USB port. The GEMS Home software is used to store and review the data collected by the HeartCheck ECG Pen Monitor. The GEMS Home software is installed onto the computer from a CD ROM by the user. The GEMS Home software CD ROM is an accessory of the applicant device.

The applicant device has low battery voltage indication function. 2 AAA batteries supply the power for the monitor.

Predicate Device(s): Handheld ECG Monitor MD100 (K093872)
HeartCheck Pen Handheld ECG with GEMS Home (K111159)

Substantial Equivalence:
The proposed device is substantial equivalent to the Handheld ECG Monitor MD100 (K093872) and HeartCheck Pen Handheld ECG with GEMS Home (K111159) devices. The proposed device has a similar intended use, technological, and design characteristics as the predicate device. Any minor differences do not introduce new issues of safety or effectiveness.

Performance Testing:
The device complies with IEC60601-1, IEC 60601-1-2 and AAMI EC38 standards. A Low Voltage Indication Validation Test, Shock Test, Random Vibration Test, Sinusoidal vibration Test, Heart Rate Accuracy Test (Shelf Life) and High, low temperature & humidity Test were all performed on the applicant device to validate its performance.

Conclusion:

The minor differences in the handheld ECG, do not introduce new issues of safety and efficacy. The HeartCheck ECG Pen with GEMS Home has been tested to demonstrate compliance with the FDA Guidance document for use as a handheld ECG, in FDA Classification Code DPS. All of the Testing performed are described and summarized in Sections 15, 17 and 18. These are the Biocompatibility, Electromagnetic Capability and Electrical Safety and Performance Testing Sections. All results demonstrate that the HeartCheck ECG Pen with GEMS Home is equivalent to the predicate device in capability and it meets all of the standard test requirements.

Therefore, the proposed HeartCheck ECG Pen with GEMS Home device is substantially equivalent to Beijing Choice Electronic Technologies - Handheld ECG Monitor MD100 (K093872), Beijing Choice Electronic Technologies – HeartCheck Pen handheld Heart Rhythm with GEMS Home (K111159). The proposed device has the same classification information, similar intended use and technological characteristics as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 17 2012

Cardio Comm Solutions, Inc.
c/o Ms. Mona Palfreyman
Director of Customer Support & Quality Assurance
201-3060 Ceder Hill Road
Victoria, BC V8T 3J5

Re: K121009
Device Name: HeartCheck ECG Pen with GEMS Home
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: March 26, 2012
Received: April 3, 2012

Dear Ms. Palfreyman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: HeartCheck ECG Pen with GEMS Home

The HeartCheck ECG Pen with GEMS Home is a telemedicine based solution that is intended to enable adult patients to record, store, transfer and display single channel ECG waveforms while involved in everyday activities anywhere. The HeartCheck ECG Pen combined with GEMS Home enables the person to send their ECG recordings to a medical service for review and interpretation by a qualified health service professional such as a physician. GEMS Home use is not intended to substitute for a hospital diagnostic ECG test. The software and hardware are not intended for recording and transmission of user's ECG signal simultaneously. Patients with implanted pacemaker or defibrillator are not recommended to use this device. GEMS Home is a simple software user interface with ECG trace viewing function.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121009